
		Technical Data Sheet	
Foliodrape® COMFORT, arthroscopy drapes		Spec.-No.:	D 6.5905g
		Department:	CMO-DOE
		Date:	2013-06-12

1. General Product Description

Foliodrape® COMFORT arthroscopy drapes is for knee-joint arthroscopy and is made of three-layer material; impermeable to moisture and bacteria; abrasion-resistant and low linting; well conformable; for sterile draping of the patient and theatre equipment. With elastic fenestrations and fluid collection pouch and velcro fastener. For arthroscopic procedures.

The Foliodrape® COMFORT arthroscopy drapes carries the CE-mark according to EU directive 93/42/EWG for medical devices and is classified as class I medical devices.

A conformity assessment has been performed for Foliodrape® COMFORT arthroscopy drapes and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Foliodrape® COMFORT arthroscopy drapes, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication


Foliodrape® COMFORT arthroscopy drapes is a disposable product for sterile draping of the patient.

3. Presentations

Art. no. 254 532	Foliodrape® COMFORT arthroscopy drape sterile, steril, 6 pieces per dispenser, 1 dispenser per transport carton
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4. Product Characteristics

Composition:	Three-layer Nonwoven-Film-Nonwoven laminate, with elastic fenestration
Nonwoven (outside):	Absorbent viscose, colour: aqua
Film:	PE-film; colour: aqua
Nonwoven (inside):	PP-SMS, colour: white
Adhesive (laminate):	Dispersion adhesive / Hotmelt
For self-adhesive drapes:	Adhesive based on synthetic rubber, latex-free; covered with silicon paper
Velcro fastener:	27 cm long
Fluid collection bag:	Transparent PE-film, with elastic fenestration and foam ring
Drainage tube:	silicone

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5. Product Requirements (typical values)

Foliodrape® COMFORT arthroscopy drapes corresponds to all requirements of European standard for surgical drapes EN 13795, for the highest performance level "High performance, critical area".

For details see Technical Data sheet of the base material (D 6.5030).


6. Labelling

Lot-No. with 9-digit code:

e.g.: 9XXX38YYY

LOT	9	XXX	38	YYY
	year of production	for internal purposes only	week of production	for internal purposes only

Expiry date:

e.g.  2014 – 01
year month

Shelf life: 5 years

The product will be sterile during this period as long as the packaging is not damaged and the storage conditions are kept.


7. Packaging

Foliodrape® COMFORT arthroscopy drape is wrapped into crepe paper, sealed into sterile packaging (peel-ing pouch) according to EN ISO 11607 and EN 868. The peel pouch is packed into folding box and transport carton, sealed with adhesive tapes and stored on euro-pallet.

Date: 2013-06-12

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i. A.



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